K002763

MAY - 4 2001

510(k) Summary

Trade Name:	RemRest
Common Name:	Nasal Continuous Positive Airway Pressure Device
Classification Name:	868.5905 Ventilator, Non-continuous, 73 BZD
Predicate Device:	SLEEPAP Nasal C.P.A.P. - K905593A Medical Industries America Inc. 2636 289th Place Adel, IA 50003

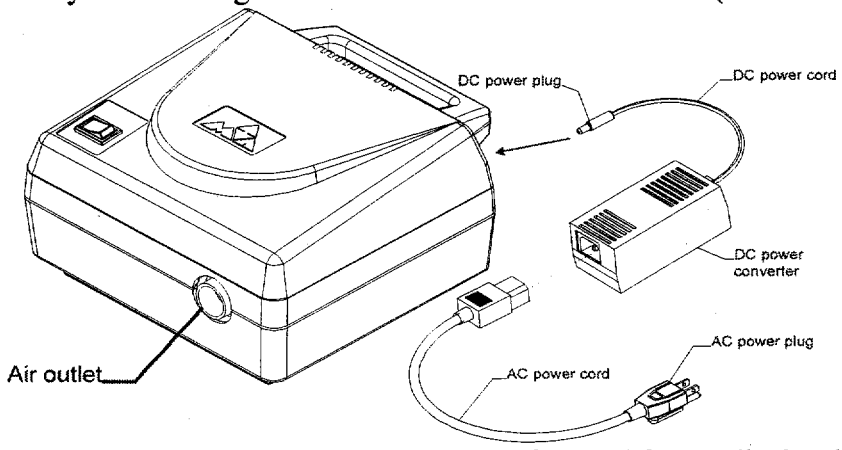
General Description

Comparison to Predicate Device

The RemRest CPAP device is not significantly different from the predicate device, SleePap which was cleared for commercial distribution per K905593A.

Device Description:

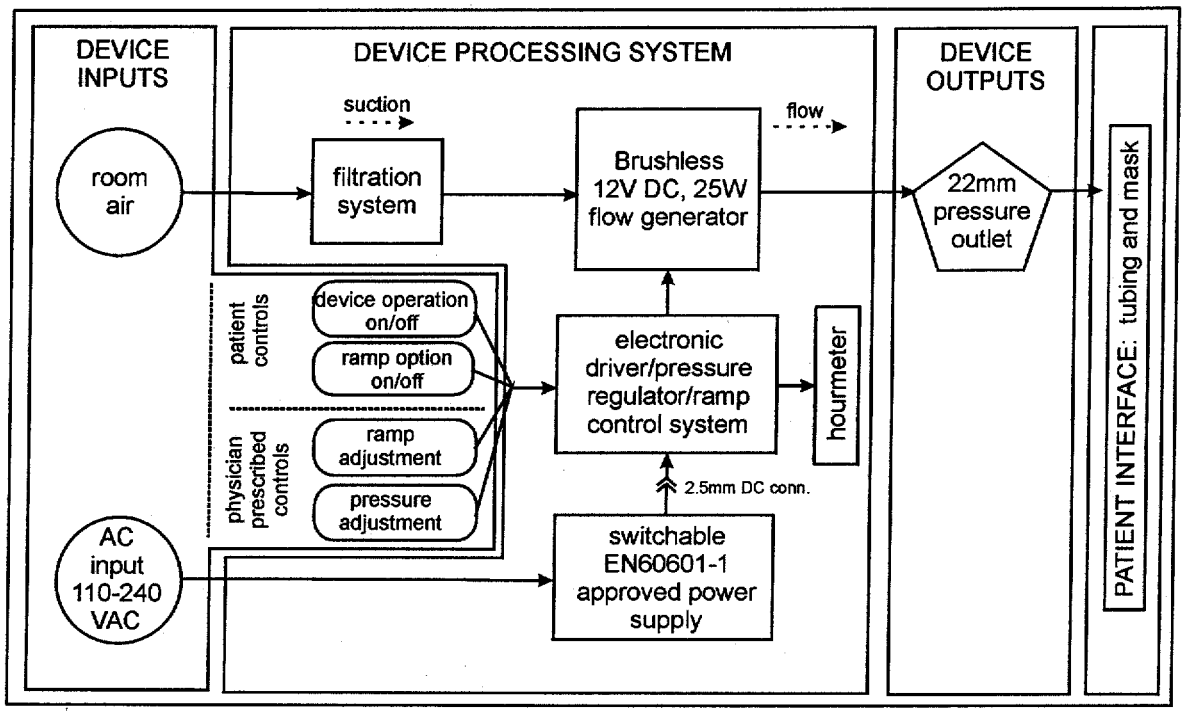
RemRest is a continuous positive airway pressure device which provides constant non-invasive air pressure for the care and treatment of adults suffering from obstructive sleep apnea. The positive pressure is dealer/clinician adjustable within the operating range. In addition, the dealer/clinician may also set an adjustable timer which will allow timed rise (ramp) to the pressure setting. The user controls are limited to an on/off switch and an option to utilize the ramp. This system is designed to be used with a 22 millimeter (smooth bore) tube and



user selected nasal masks which are manufactured for Medical Industries. These are the same masks and tubes utilized with the SleePap device. The exhaust is an orifice which may be part of the adapter between the tubing and the patient mask or may be a part of the mask.

With its 12 VDC external power supply/transformer, the RemRest is suitable for operation in most electrical power environments ranging from 110 to 240 volts alternating current (VAC) and 47 to 63 Hertz. The use of the external power supply/transformer will allow ease of exchange of cords for international plug requirements. The RemRest with the DC power cord will work also on any 12V DC outlet allowing the patient the ability to use the device in their motor or recreational vehicles. There are no batteries incorporated into the device – it must either be run on an AC or DC power source. The CPAP is not intended for use in emergency vehicles.

C1001RemRest functional device diagram



Note: Pressure regulation is accomplished by maintaining a constant motor speed. This is done by the microprocessor counting the motor RPM pulses and then changing the motor speed voltage supplied to the motor drive circuit as required to maintain constant speed.

The device is not life-supporting or life-sustaining.

Neither the device nor its accessories are sterile.

The device and the air filter are for multiple use. The other accessories such as the patient circuit, tubing and masks are for single patient use.

The device is for prescription use and is labeled accordingly.

The device does not contain a drug or biological product as a component, however it may be used to provide the patient with supplemental oxygen. The appropriate cautionary statements are found in the labeling.

The device is not a part of a kit.

The device is not software driven.

Summary of Performance Testing:

1. Functional Testing: In addition to the normal performance checks, non-clinical performance testing of the RemRest device was done to confirm at three different settings (5 cm, 10 cm and 15 cm H_20) the pressure remained stable. Over the course of the test, the readings for the test device stayed within 10% of the desired setting – a variation due in part to the method for blocking off the flow of air through the mask. Attachment A-5 includes the information recorded through the course of the test as well as a non-controlled copy of the test instructions for the RemRest and for the predicate device. The device passed all the tests.

2. Electrical Safety/EMI/RFI/Environmental: The device successfully met the requirements of electrical safety/EMI/RFI and the environmental testing as outlined in the consensus standard EN60601-1 and EN60601-1-2. The testing was performed by certified test facilities.

3. No clinical studies were required to support substantial equivalence determination.

Conclusions

Performance testing verified the RemRest CPAP device meets the performance requirements and will operate safely in its intended environment and will be effective in fulfilling its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2001

Ms. Anne B. Carlson
Medical Industries America Inc.
2636 289th Place
Adel, IA 50003-8021

Re: K002763
Remrest
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: February 6, 2001
Received: February 7, 2001

Dear Ms. Carlson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

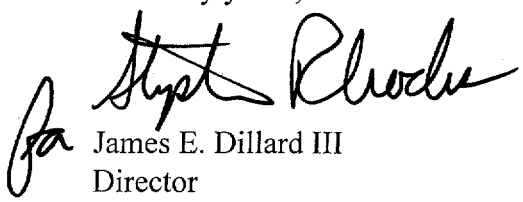
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002763

Device Name: RemRest

Indications for Use:

The Medical Industries America Inc. RemRest device is designed to provide continuous positive airway pressure via a nasal mask, headgear and combination of breathing circuit accessories for the treatment of adult obstructive sleep apnea patients.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number K002763

Prescription Use X **OR** **Over the Counter Use** _____
(Per 21 CFR 801.109) **(Optional Format 1/2/96)**